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10/1

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,767	03/17/2000	Wolfgang Kreiss	LeA 33 072	3608
35969	7590	09/21/2004	EXAMINER	
JEFFREY M. GREENMAN BAYER PHARMACEUTICALS CORPORATION 400 MORGAN LANE WEST HAVEN, CT 06516			YANG, NELSON C	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/527,767	KREISS ET AL.
Examiner	Art Unit	
Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 July 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 27-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 27-43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Response to Amendment***

- I.      Applicant's amendment of claims 27, 28, 30-33, and 38-43 are acknowledged and has been entered.
  1.      Applicant's cancellation of claim 44 is acknowledged and has been entered.
  2.      Claims 27-43 are currently pending.

### ***Rejections Withdrawn***

- II.     Applicant's arguments, see page 5, filed July 1, 2004, with respect to the rejections under 35 U.S.C. 112, first paragraph, have been fully considered and are persuasive. The rejection of claims 28, 38-43 under 35 U.S.C. 112, first paragraph, has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

- III.    The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3.      Claims 27-29, 31-39, 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Simpson et al [US 6,117,643].

Simpson et al teach a biosensor comprising bioreporters enclosed in polymer matrix (column 7, lines 65-67). Simpson et al specifically teach encapsulated cells that can be formed into sheets or thickness or diameter desired, where cells may be added to molten agar or agarose,

where gelation occurs as the agar or agarose cools to room temperature (column 68, lines 33-51).

The cells comprise a recombinant vector comprising a nucleic-acid segment encoding one or more bioluminescent polypeptides (column 22, lines 60-65), and are located on discrete areas of the matrix (figs. 9A-D). Simpson et al further teach a photodetector (column 9, lines 1-10).

4. With respect to claim 28, Simpson et al further teach a substrate that contains the matrix and the photodetector as well as additional circuitry that processes and transmits the signal.

5. With respect to claim 29, the matrix may comprise agar or agarose (column 68, lines 33-51).

6. With respect to claim 31, Simpson et al teach that catalytic antibodies with sufficiently fast antigen dissociation rates to allow reversible measurements in real time may also be used (column 21, lines 5-26).

7. With respect to claim 32, Simpson et al teach the use of different bioreporters (figs 9A-D, column 5, lines 28-30).

8. With respect to claim 33, the cells may have a second signal transducer to function as an internal control signal, which may serve as a dynamic baseline with which to compare the target signal (column 22, lines 23-32).

9. With respect to claims 34-35, Simpson et al teach the incubation of encapsulated HK44 with groundwater and 0.1xYEPG medium, and the use of simple and complex inducer solutions (column 65, lines 1-28).

10. With respect to claim 36, Simpson et al teach the use of fluorescent and enzymatic labels (column 31, lines 20-35).

11. With respect to claim 37, Simpson et al teach that layers of encapsulation can also be produced (column 69, lines 35-40).
12. With respect to claims 38-39, Simpson et al teach that cells may be added to molten agar or agarose of 1% to 5% (column 68, lines 48-50). Therefore, in 50 mL of the agar or agarose, there would be 2 to 10 mL of cells.
13. With respect to claims 41-43, the sheets can be 0.1-2 mm (column 68, lines 39-41).

***Claim Rejections - 35 USC § 103***

IV. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al [US 6,117,643] in view of Ribi [US 5,156,810].

Simpson et al teach biosensors comprising bioreporters enclosed in polymer matrix as discussed above. Simpson et al do not specifically teach polyacrylates as the polymer.

Ribi, however, teaches that polyacrylate is inert and has good electrical insulating properties, is smooth at the molecular level, and has good adhering properties (column 3, lines 27-35).

Therefore it would have been obvious to use polyacrylate as the polymer in the biosensors of Simpson et al, as suggested by Ribi, since polyacrylate is inert and has good electrical insulating properties, is smooth at the molecular level, and has good adhering

properties, and therefore would not interfere with the optical detection of the presence of substances.

15. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al [US 6,117,643].

While Simpson et al teach biosensors comprising bioreporters enclosed in polymer matrix as discussed above, Simpson et al fail to specifically teach that the biosensor has an optical density of 0.6 to 1.4 at 660 nm. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore it would have been obvious through normal optimization techniques to a person of ordinary skill in the art to obtain a biosensor with an optical density of 0.6 to 1.4 at 660 nm.

#### ***Response to Arguments***

V. Applicant's arguments with respect to the rejections claims 27-43 under 35 U.S.C. 102 and 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

VI. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

